K132165

510(k) Summary

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21 CFR. Part 807.92.

1) Submitter's name, address, telephone number, contact person

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Date prepared: June 12, 2013

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:	Picture Archiving and Communications Systems Workstation
Proprietary Name:	QLAB Quantification Software
Classification Name:	CFR 892.2050, system, image processing, radiological, 90 LLZ, Class II

3) Substantially Equivalent Devices

Philips Ultrasound believes that the modified QLAB a2DQ, aCMQ, MVN, and Heart Model Q-Apps are substantially equivalent to the previously cleared iU22 with 2DQ (K042540), QLAB with MVQ (K070792), QLAB CMQ (K120525), and QLAB Heart Model (130159).

4) Device Description

QLAB Quantification software is available either as a stand-alone product that can function on a standard PC, on board a dedicated workstation, or on-board Philips' ultrasound systems. It can be used by trained healthcare professionals for the on-line and off-line review and quantification of ultrasound studies in healthcare facilities/hospitals.

The QLAB Quantification software application package is designed to view and quantify image data acquired on Philips ultrasound products. The four modified plug-ins, a2DQ, aCMQ , MVN, and Heart Model are applications within Philips QLAB Quantification software.

Automated 2D Quantification (a2DQ)
The 2DQ Q-App for the display of 2D ultrasound images was originally submitted with Philips iU22 Ultrasound system (K042540). 2DQ has been renamed a2DQ. It computes areas, volumes and advanced parameters for LV systolic and diastolic function including: LV Ejection Fraction (EF), Peak Ejection Rate (PER), Peak Rapid Filling Rate (PRFR) and Atrial Filling Fraction (AFF). It also computes End Systolic Volume (ESV) and End Diastolic Volume (EDV). The Color Kinesis (CK) tool provides color-coded visualization of global and regional wall motion. a2DQ has been modified to improve workflows including semi-automated border detection for cardiac chambers and vessel cavities.

Automated Cardiac Motion Quantification (aCMQ)
CMQ modifications were last addressed in QLAB 510(k) K120525. CMQ has been renamed aCMQ aCMQ provides an angle-independent analysis of regional myocardial-tissue velocity, displacement, strain, and strain rate, using the speckle-tracking technology. It generates measurements of the global and regional functions and reports them in a table, a 17-segment bull's eye, and a variety of waveform displays. It additionally computes LV Ejection Fraction (EF), End Systolic Volume (ESV) and End Diastolic Volume (EDV). aCMQ has been modified to automatically draw a region of interest based on the selected anatomical view, (user can edit the ROI if desired).

Mitral Valve Navigator (MVN)
The MVQ plug-in was submitted in QLAB 510(k) K070792. The application, renamed Mitral Valve Navigator (MVN), was originally designed as a manual segmentation interface that would allow for detailed segmentation of the mitral valve annulus, leaflets, and papillary muscle. However, as segmentation using the interface is entirely manual, the approximate time to complete the segmentation ranges from 5-15 minutes, depending on the user's familiarity with the interface, the quality of the image, and the user's knowledge of the mitral valve and experience in interpreting 3D echo images. The modification to MVN (MVQ) updates the application with improved task guidance and semi-automation for greater efficiency and ease of use. The modification focused primarily on decreasing the required workflow time by identifying bottlenecks in the workflow.

Heart Model Quantification (HM)
The Heart Model Q-App (K130159) provides one-click visualization of all four cardiac chambers, and quantifies the left ventricle (LV) and left atrium (LA) using a 3D Volume image from an apical four-chamber view. It provides the LV and LA volume, stroke volume, and LV ejection fraction (EF) at end-systole and end-diastole (ED) for adult hearts. It easily delivers the routine 2D views from the 3D volume. Measurements are closely correlated to cardiac MR and are exported to the report. The modified Heart Model application allows users to override border placement. The user may edit the border by clicking and dragging the border to the desired location. Numeric quantification will be updated based upon user placement of borders.

The QLAB modifications described in this Special 510(k) submission do not alter the intended use of the QLAB Quantification software with the modified a2DQ, aCMQ, MVN, and Heart Model Q-Apps.

5) Indications for Use

QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips Healthcare ultrasound products.

6) Technological characteristics

The QLAB Quantification software with the modified Q-Apps has the same technological characteristics as the legally marketed device.

7) Non-clinical performance data

No performance standards for PACS systems or components have been issued under the authority of Section 514. The a2DQ, aCMQ, MVN, and Heart Model modifications were tested in accordance with Philips verification and validation processes. Verification and validation data support the modified QLAB software for the a2DQ, aCMQ, MVN, and Heart Model software relative to the unmodified QLAB software.

Design Control activities to assure the safe and effective performance of the modified plug-ins included, but were not limited to:

- Requirements Review
- Design Review
- Risk Management
- Verification and Validation Testing

Verification and Validation testing concluded that the modified QLAB Q-Apps are safe and effective and introduced no new risks.

8) General Safety and Effectiveness Concerns

The device labeling contains operating instructions for the safe and effective use of the QLAB Quantification software with the modified Q-Apps.

9) Conclusions

Verification and Validation activities required to establish the performance, functionality, and reliability characteristics of the modified QLAB Q-Apps with respect to the predicate were performed. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Testing performed demonstrated that the QLAB Quantification software with modified Q-Apps meets all defined reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 9, 2013

Philips Ultrasound, Inc.
% Mr. Mark Job
Responsible Third Party Official
1394 25th Street NW
BUFFALO MN 55313

Re: K132165
Trade/Device Name: QLAB Quantification Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 10, 2013
Received: July 12, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132165

Device Name: QLAB Quantification Software

Indications for Use:

QLAB Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips Healthcare ultrasound products.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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